

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-57 (Canceled)

58. (New) A method for the diagnosis of a neurodegenerative disorder in a mammalian subject comprising:

- a. providing a body fluid sample of said subject;
- b. concentrating proteins comprised within said sample by suitable means;
- c. contacting the concentrated sample obtained in step (b) with a sufficient amount of a protein which has a beta-sheet structure, under conditions suitable to allow the formation of aggregates, said aggregates comprise a protein associated with said neurodegenerative disorder; and
- d. measuring aggregate formation by suitable means, whereby the presence of aggregates in said sample indicates that said subject carries said neurodegenerative disorder.

59. (New) The method according to claim 58, wherein the measurement of aggregate formation in said step (d) comprises the following steps:

- (i) adding to the mixture obtained in step (c) a binding material capable of binding aggregates of proteins associated with said neurodegenerative disorder;
- (ii) applying the sample obtained in step (i) onto a solid support; and
- (iii) detecting a visual signal which indicates the presence of aggregates comprising a neurodegenerative disorder- associated protein in said tested sample.

60. (New) The method according to claim 59, further comprising the step of separating said aggregates from said mixture by suitable means, prior to the addition of said binding material, wherein said suitable means is selected from the group consisting of proteinase K digestion, dialysis and centrifugation.

61. (New) The method according to claim 59, wherein said binding material is selected from the group consisting of an antibody, a peptide, a substance having affinity to a specific compound in said aggregate and specific dye.

62. (New) The method according to claim 61, wherein said binding material is an antibody which specifically recognizes said protein which has a beta-sheet structure.
63. (New) The method according to claim 58, wherein said protein which has a beta-sheet structure is selected from the group consisting of IgG light chain (LC), human Bence Jones (BJ) protein and recombinant PrP protein, preferably, IgG light chain (LC).
64. (New) The method according to claim 58, wherein said neurodegenerative disorder is any one of Alzheimer's disease, multiple sclerosis, and spongiform encephalopathy selected from Creutzfeldt-Jakob disease (CJD), Gerstmann-Straussler-Scheinker Syndrome (GSS), Kuru, scrapie and bovine spongiform encephalopathy (BSE).
65. (New) The method according to claim 64, wherein said mammalian subject is selected from the group consisting of humans, sheep, goats, bovines, minks, hamsters and cats.
66. (New) The method according to claim 58, wherein said body fluid sample is selected from the group consisting of: blood, lymph, milk, urine, faeces, semen, brain extracts, spinal cord fluid (SCF), appendix, spleen and tonsillar tissue extracts samples.
67. (New) The method according to claim 58, wherein concentrating the proteins in said sample is performed by centrifugation and precipitation.
68. (New) The method according to claim 58, wherein said neurodegenerative disorder-associated protein is the abnormal isoform of prion protein (PrP<sup>Sc</sup>).
69. (New) A method according to claim 58, for the diagnosis of a spongiform encephalopathy in a mammalian subject comprising:
  - (a) providing a urine sample of said subject;
  - (b) concentrating proteins comprised within said sample;
  - (c) contacting the concentrated sample obtained in step (b) with a sufficient amount of IgG LC, under conditions suitable to allow the formation of aggregates, which

- aggregates comprise the abnormal isoform of prion protein (PrP<sup>SC</sup>);
- (d) adding Congo Red to the sample mixture obtained in step (c), in an amount sufficient for detection of aggregates comprising the abnormal isoform of the prion protein (PrP<sup>SC</sup>);
  - (e) applying the sample obtained in step (d) onto a nitrocellulose membrane; and
  - (f) detecting a visual signal indicating the presence of aggregates comprising the abnormal isoform of prion protein (PrP<sup>SC</sup>) in said tested urine sample; whereby the presence of said aggregates in said sample indicates that said subject carries a prion disease.
70. (New) The method according to claim 69, wherein diagnosis of said spongiform encephalopathy is performed prior to or after onset of clinical symptoms.
71. (New) A method for detecting the presence of a neurodegenerative disorder-associated protein in a sample of a subject, said method comprising the steps of:
- (a) providing a body fluid sample of said subject;
  - (b) concentrating proteins comprised within said sample by a suitable means;
  - (c) contacting the concentrated sample obtained in step (b) with a sufficient amount of a protein which has a beta-sheet structure, under conditions suitable to allow the formation of aggregates, which aggregates comprising said neurodegenerative disorder-associated protein; and
  - (d) measuring aggregate formation by suitable means.
72. (New) The method according to claim 71, for detecting the presence of the abnormal isoform of prion protein (PrP<sup>SC</sup>) in a urine sample of a subject, said method comprising the steps of:
- (a) providing a urine sample of said subject;
  - (b) concentrating proteins comprised within said sample;
  - (c) contacting the concentrated sample obtained in step (b) with a sufficient amount of IgG LC, under suitable conditions allowing the formation of aggregates comprising the abnormal isoform of prion protein (PrP<sup>SC</sup>);
  - (d) adding Congo Red to the sample mixture obtained in step (c), in an amount

sufficient for detection of formation of aggregates which comprise the abnormal isoform of prion protein (PrP<sup>SC</sup>);

- (e) applying the sample obtained in step (d) onto a nitrocellulose membrane; and
- (f) detecting a visual signal indicating the presence of aggregates comprising the abnormal isoform of prion protein (PrP<sup>SC</sup>) in said tested urine sample; whereby the presence of said aggregates in said sample is indicative of the presence of the abnormal isoform of prion protein (PrP<sup>SC</sup>) in said sample.

73. (New) A kit for the diagnosis of a neurodegenerative disorder in a mammalian subject, comprising:

- (a) means for obtaining a sample from a tested mammalian subject;
- (b) means for concentrating proteins in said sample;
- (c) a protein which has a beta sheet structure;
- (d) means for measuring aggregate formation in said sample;
- (e) optionally, suitable buffers;
- (f) instructions for carrying out the detection of the presence of aggregates comprising a neurodegenerative disorder-associated protein in said sample; and
- (g) optionally, means for separating said aggregates from said sample prior to measuring aggregate formation.

74. (New) The kit according to claim 73, wherein said means for measuring aggregate formation is a binding material capable of binding said neurodegenerative disease associated protein aggregate, preferably, said binding material is selected from the group consisting of an antibody, a peptide, a substance having affinity to a specific compound in said aggregate and a specific dye.

75. (New) The kit according to claim 72, wherein said binding material is any one of Congo Red, Thioflavin-T and Thioflavin-S.

76. (New) The kit according to claim 72, wherein said binding material is an antibody which specifically recognizes said protein which has a beta-sheet structure.

77. (New) The kit according to claim 71, further comprising solid support for binding proteins in said sample.
78. (New) The kit according to claim 71, wherein said protein which has a beta-sheet structure is selected from the group consisting of IgG light chain (LC), human Bence Jones (BJ) protein and recombinant PrP protein.
79. (New) The kit according to claim 78, wherein said neurodegenerative disorder is any one of Alzheimer's disease, multiple sclerosis, and spongiform encephalopathy selected from, Creutzfeldt-Jakob disease (CJD), Gerstmann-Straussler-Scheinker Syndrome (GSS), Kuru, scrapie and bovine spongiform encephalopathy (BSE).
80. (New) The kit according to claim 79, wherein said mammalian subject is selected from the group consisting of humans, sheep, goats, bovines, minks, hamsters and cats.
81. (New) The kit according to claim 80, wherein said body fluid sample is selected from the group consisting of blood, lymph, milk, urine, faeces, semen, brain extracts, spinal cord fluid (SCF), appendix, spleen and tonsillar tissue extracts samples.
82. (New) The kit according to claim 81, wherein said neurodegenerative disorder-associated protein is the abnormal isoform of prion protein (PrP<sup>SC</sup>).
83. (New) A diagnostic composition for the detection of a neurodegenerative disorder in a mammalian subject, which composition comprises as an effective ingredient a sufficient amount of a protein which has a beta-sheet structure.